



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Inventor(s): Lehmann, et al.

Serial No. 10/706,701, filed November 12, 2003  
(Ref. No. 21435 US)

For: **TREATMENT OF DISTURBANCES OF IRON DISTRIBUTION**

**INFORMATION DISCLOSURE STATEMENT**

Nutley, New Jersey 07110  
February 11, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants respectfully direct the Examiner's attention to the documents listed on enclosed Form PTO-1449.

Documents B1-B20, and C1-C8 listed on Form PTO-1449 are enclosed. Document B4 is not in the English language and is abstracted in Document C7. Document B19, is not in the English language and is abstracted in Document C8. Copies of documents A1 to A20 are not enclosed as they are U.S. patents.

Copies of documents B21-B26, and C9-C24 are not being submitted as they are made of reference in related U.S. application Serial No. 10/047,749, filed October 23, 2001, pending.



Serial No. 10/706,701  
Filed: November 12, 2003

Consideration of all the documents cited on Form PTO-1449 is requested.


The Examiner's attention is particularly directed to

- P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois.

The Examiner's attention is also directed to co-pending, co-owned US Serial No. 10/634,477, filed August 4, 2003 (Case Docket No. 21368), a copy of which is enclosed.

Since the Information Disclosure Statement is submitted before the mailing of the first Office Action on the merits or within three months of the filing date for the above application, no fee is due.

Respectfully submitted,

  
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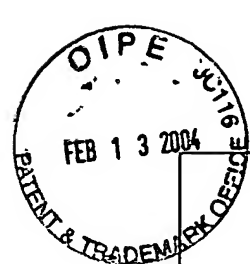
Enclosures  
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| Substitute for form 1449A/PTO                    |                          |                         |                                      | Complete if Known                                  |  |   |                |
|--|--------------------------|-------------------------|--------------------------------------|--|--|---|----------------|
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT |                          |                         |                                      | Application Number                                 | 10/706,701   |   |                |
| (Use several sheets if necessary)                |                          |                         |                                      | Filing Date  | November 12, 2003                                      |   |                |
|  |                          |                         |                                      | First Name Inventor                                | Lehmann, et al.  |   |                |
| Sheet  | 1                        | of                      | 3                                    | Attorney Docket Number                             | 21435 US   |   |                |
| <b>U.S. PATENT DOCUMENTS</b>                     |                          |                         |                                      |  |  |   |                |
| Examiner<br>Initials <sup>1</sup>                | Cite<br>No. <sup>1</sup> | U.S. Patent Document    |                                      | Name of Patentee or Applicant of<br>Cited Document | Date of Publication of<br>Cited document<br>MM-DD-YYYY |   |                |
|  |                          | Number                  | Kind Code <sup>2</sup><br>(if known) |  |  |   |                |
|  | A1                       | 4,179,337               |                                      | Davis et al.                                       | 12/18/1979   |   |                |
|  | A2                       | 4,745,099               |                                      | Akamatsu et al.                                    | 05/17/1988   |   |                |
|  | A3                       | 5,272,071               |                                      | Chappel  | 12/21/1993   |   |                |
|  | A4                       | 5,324,650               |                                      | Obzansky et al.                                    | 06/28/1994   |   |                |
|  | A5                       | 5,359,030               |                                      | Ekwuribe   | 10/25/1994   |   |                |
|  | A6                       | 5,376,632               |                                      | Konings et al.                                     | 12/27/1994   |   |                |
|  | A7                       | 5,541,158               |                                      | Vance et al.                                       | 07/30/1996   |   |                |
|  | A8                       | 5,641,670               |                                      | Treco et al.                                       | 06/24/1997   |   |                |
|  | A9                       | 5,672,662               |                                      | Harris et al.                                      | 09/30/1997   |   |                |
|  | A10                      | 5,681,811               |                                      | Ekwuribe   | 10/28/1997   |   |                |
|  | A11                      | 5,733,746               |                                      | Treco et al.                                       | 03/31/1998   |   |                |
|  | A12                      | 5,733,761               |                                      | Treco et al.                                       | 03/31/1998   |   |                |
|  | A13                      | 5,981,214               |                                      | Skoultchi  | 11/09/1999   |   |                |
|  | A14                      | 5,994,127               |                                      | Selden et al.                                      | 11/30/1999   |   |                |
|  | A15                      | 6,333,306               |                                      | Lehmann et al.                                     | 12/25/2001   |   |                |
|  | A16                      | 6,340,742               |                                      | Burg et al.  | 01/22/2002   |   |                |
|  | A17                      | 6,372,715               |                                      | Kaltwasser et al.                                  | 04/16/2002   |   |                |
|  | A18                      | 6,528,313               |                                      | Le Mouellic et al.                                 | 03/04/2003   |   |                |
|  | A19                      | 6,583,272               |                                      | Bailon   | 06/24/2003   |   |                |
|  | A20                      | US 2002/0160956 A1      |                                      | Lehmann et al.                                     | 10/2002  |   |                |
| <b>FOREIGN PATENT DOCUMENTS</b>                  |                          |                         |                                      |  |  |   |                |
| Examiner<br>Initials <sup>1</sup>                | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                                      |  | Name of Patentee or<br>Applicant of Cited Document     | Date of<br>Publication of<br>Cited Document<br>MM-DD-YYYY | T <sup>6</sup> |
|  |                          | Office <sup>3</sup>     | Number <sup>4</sup>                  | Kind<br>Code <sup>5</sup><br>(if<br>known)         |  |   |                |
|  | B1                       | WO 93/09222             |                                      |  | Transkaryotic Therapies, Inc.                          | 05/13/1993  |                |
|  | B2                       | WO 94/12650             |                                      |  | Transkaryotic Therapies, Inc.                          | 06/09/1994  |                |
|  | B3                       | WO 95/31560             |                                      |  | Transkaryotic Therapies, Inc.                          | 11/23/1995  |                |
|  | B4                       | WO 90/11354             |                                      |  | Institut Pasteur                                       | 10/04/1990  |                |
|  | B5                       | WO 91/06667             |                                      |  | Cell Genesys Inc.                                      | 05/16/1991  |                |
|  | B6                       | WO 91/09955             |                                      |  | Applied Research Systems                               | 07/11/1991  |                |
|  | B7                       | WO 01/02017             |                                      |  | F.Hoffmann-La Roche AG                                 | 01/11/2001  |                |
|  | B8                       | EP 1064951              |                                      |  | F.Hoffmann-La Roche AG                                 | 01/03/2001  |                |
| Examiner<br>Signature                            |                          |                         |                                      |  | DATE<br>CONSIDERED                                     |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation or abstract is attached.



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|---|---|----|--------------------------|------------------------|----------|
| Substitute for form 1449A/PTO<br><b>INFORMATION DISCLOSURE<br/>         STATEMENT BY APPLICANT</b><br><br>(Use several sheets if necessary) |   |    | <b>Complete if Known</b> |                        |          |
|   |   |    | Application Number       | 10/706,701             |          |
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|   |   |    | First Name Inventor      | Lehmann, et al.        |          |
| Sheet   | 2 | of | 3                        | Attorney Docket Number | 21435 US |

### FOREIGN PATENT DOCUMENTS

| Examiner Initials <sup>7</sup> | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | T <sup>6</sup> |
|--------------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|----------------|
|                                |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |   |  |                |
|                                | B9                    | EP                      | 539167              |                                   | Ortho Pharmaceutical Corp.                      | 04/28/1993                                       |                |
|                                | B10                   | EP                      | 605963              |                                   | Ortho Pharmaceutical Corp.                      | 07/13/1994                                       |                |
|                                | B11                   | WO                      | 93/25212            |                                   | Amgen Inc.                                      | 12/23/1993                                       |                |
|                                | B12                   | WO                      | 94/20069            |                                   | Amgen Inc.                                      | 09/15/1994                                       |                |
|                                | B13                   | WO                      | 95/11924            |                                   | Enzon, Inc.                                     | 05/04/1995                                       |                |
|                                | B14                   | EP                      | 584876              |                                   | Sterling Winthrop Inc.                          | 03/02/1994                                       |                |
|                                | B15                   | WO                      | 92/16555            |                                   | Enzon, Inc.                                     | 10/01/1992                                       |                |
|                                | B16                   | WO                      | 94/28024            |                                   | Enzon, Inc.                                     | 12/08/1994                                       |                |
|                                | B17                   | WO                      | 97/04796            |                                   | Protein Delivery, Inc.                          | 02/13/1997                                       |                |
|                                | B18                   | WO                      | 98/32466            |                                   | Polymasc Pharmaceutical PLC                     | 07/30/1998                                       |                |
|                                | B19                   | DE                      | 3924705             |                                   | Boehringer Mannheim GmbH                        | 01/31/1991                                       |                |
|                                | B20                   | WO                      | 01/87329            |                                   | F.Hoffmann-La Roche AG                          | 11/22/2001                                       |                |
|                                | B21                   | EP                      | 640619              |                                   | Amgen Inc.                                      | 03/01/1995                                       |                |
|                                | B22                   | EP                      | 0411678             |                                   | Genetics Institute Inc.                         | 02/06/1991                                       |                |
|                                | B23                   | EP                      | 0205564             |                                   | Genetics Institute Inc.                         | 12/30/1986                                       |                |
|                                | B24                   | EP                      | 0286439             |                                   | Ortho Pharmaceutical Corp.                      | 10/12/1988                                       |                |
|                                | B25                   | WO                      | 97/09996            |                                   | Boehringer Mannheim GmbH                        | 03/20/1997                                       |                |
|                                | B26                   | WO                      | 98/41226            |                                   | Boehringer Mannheim GmbH                        | 09/24/1998                                       |                |

### NON PATENT LITERATURE DOCUMENTS

| Examiner Initials <sup>7</sup> | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup>  |
|--------------------------------|-----------------------|---|-----------------|
|                                | C1                    | P. Lehmann, M. Volkmann, J. Lotz, A. Baldauf, R. Roeddiger, poster presented at the AACC/CSCC, Annual Meeting, July 29 - August 2, 2001, Chicago Illinois   |                 |
|                                | C2                    | March J., Advanced Organic Chemistry, McGraw-Hill, 1977, pgs. 375-376   |                 |
|                                | C3                    | Grasetti, D. R. & Murray, J. F., J. Appl. Biochem. Biotechnol. 119, pgs. 41-49, 1967  |                 |
|                                | C4                    | Morpurgo M. et al., J. Bioconj. Chem. (1996) Vol. 7, pgs. 363-368   |                 |
|                                | C5                    | Hermanson, G. T. Bioconjugate Techniques Academic Press, San Diego (1996) pgs. 147-148  |                 |
|                                | C6                    | Annable, et al. Bull. Wld. Hlth. Org. (1972) Vol. 47 pgs. 99-112  |                 |
|                                | C7                    | Abstract corresponding to WO 90/11354 (B4)  |                 |
|                                | C8                    | Abstract corresponding to DE 3924705 (B19)  |                 |
| Examiner Signature             |                       |   | DATE CONSIDERED |

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|--------------------------------|-----------------------|---|----------------|
|                                | C9                    | Grützmacher P., et al., <i>Clinical Nephrology</i> , vol. 38, pp 92-97, 1992  |                |
|                                | C10                   | Wick, M.; Pinggera, W.; Lehmann, P., <i>Eisenstoffwechsel Diagnostik und Therapie der Anämien</i> , 3 <sup>rd</sup> Edition, Springer, Wien, NY, pp 5-14, 38-55, 65-80, 94-98, Sept. 1996   |                |
|                                | C11                   | Sunder-Plassmann G., et al., <i>Journal of the American Society of Nephrology</i> , 5, (3), pp 478 (1994).  |                |
|                                | C12                   | Gasche C., et al., <i>Dig. Dis. Sci.</i> , 39, (9) pp 1930-4 (1994).  |                |
|                                | C13                   | Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 10, (11), pp 2070-2076 (1995).  |                |
|                                | C14                   | Mercuriali F. et al., <i>Erythropoiesis: New Dimensions in the Treatment of Anaemia</i> , 6/3, pp 67-76, (1995).  |                |
|                                | C15                   | Sunder-Plassmann G., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (9), pp 1797-1802, (1996).  |                |
|                                | C16                   | Taylor J. E., et al., <i>Nephrology Dialysis Transplantation</i> , 11, (6), pp 1079-1083, (1996).   |                |
|                                | C17                   | Breymann, et al., <i>Eur. J. Clin. Invest.</i> , pp 123-30.   |                |
|                                | C18                   | Goodnough, et al., <i>Haematology</i> , 1(2), pp 163-166.   |                |
|                                | C19                   | MacDougall (1994) Monitoring of Iron Status & Iron Supplementation in Patients Treated with Erythropoietin. <i>Current Opinion in Nephrology &amp; Hypertension</i> 3(6) pgs. 620-625   |                |
|                                | C20                   | Taylor et al. (1996) Regular low-dose Intravenous Iron Therapy Improves Response to Erythropoietin in Haemodialysis Patients. <i>Nephrology, Dialysis, &amp; Transplantation</i> 11(6) pgs. 1079-1083   |                |
|                                | C21                   | Means, Jr. (1995) Erythropoietin in the Treatment of Anemia in Chronic Infectious, Inflammatory, & Malignant Diseases. <i>Current Opinion in Hematology</i> 2(3) pgs. 210-213   |                |
|                                | C22                   | Adamson (1996) Erythropoietin, Iron Metabolism, & Red Blood Cell Production. <i>Seminars In Hematology</i> 33(2) pgs. 5-9   |                |
|                                | C23                   | Mercuriali & Inghilleri (1995) Iron Administration to Optimize the Effect of r-HuEPO in the Surgical Setting. <i>Erythropoiesis: New Dimensions in the Treatment of Anemia</i> 6(3) pgs. 67-76  |                |
|                                | C24                   | Pincus et al. (August, 1990) Multicultural Study of Recombinant Human Erythropoietin in Correction of Anemia in Rheumatoid Arthritis. <i>The American Journal of Medicine</i> 89(2) pgs. 161-168.   |                |

|                    |                 |
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